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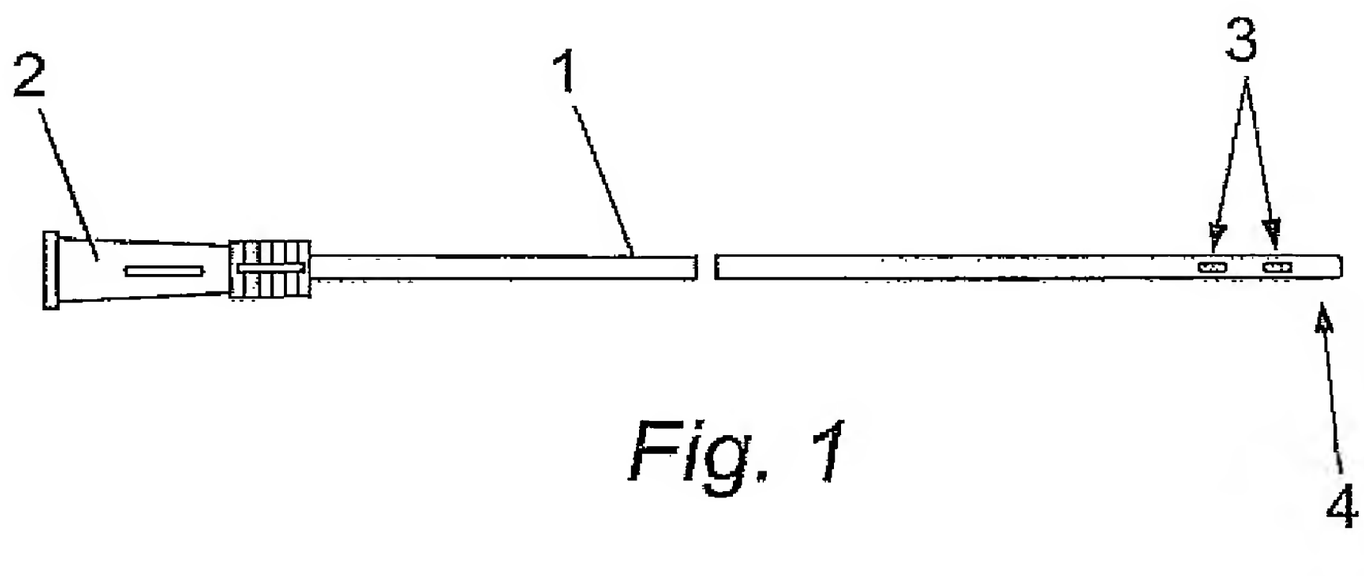

Fig. 1

(57) Abstract: The present invention concerns a catheter for medical purposes, such as for insertion into a body opening for draining fluids, wherein the catheter comprises a flexible tube having a distal end region wherein the tube is provided with at least one draining opening, characterised in that the peripheral edge on the outside of the tube is provided with a curvature for creating a smooth transition between the exterior surface of the tube and the substantially radially oriented cut constituting the opening side and wherein said curvature is a rounded edge with a curvature radius between 0.2-0.6 mm. The invention further concerns a method of making such catheter and an apparatus for performing this method.

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A catheter and a method and an apparatus for making such catheter

The present invention relates to a catheter for medical purposes, such as for insertion into a body opening for draining fluids, wherein the catheter comprises a flexible tube having a distal end region wherein the tube is provided with at least one draining opening. The invention further relates to a method of making such catheter and an apparatus for performing such method.

A catheter includes a flexible tube with a distal end, which may be open or closed. The catheter is inserted into a body opening for draining fluids. In particular, the catheter may be a urinary catheter for insertion into a urinary pathway for collecting the fluids in this pathway.

In the distal end region of the catheter, the tube is provided with a number of openings for colleting fluid and draining the body opening, in particular the urinary pathway. A catheter of such kind is known from e.g. US-A-5,919,170. As shown in this U.S. patent, the openings are preferably elongated to achieve a good fluid collecting capacity. These openings are usually punched into the tube. Examples of such catheters are known from e.g. GB-A-2 230 702 and US-A-3,995,518.

The catheter must be carefully inserted and removed to avoid damaging the tissue of the pathway. This can be a problem with these known catheters, since the openings have a relatively sharp edge which can damage the soft tissue of the pathway when the catheter is moved longitudinally or rotated in the pathway during inserted or retracted. The catheters are usually produced in PVC or PUR so that a soft flexible tube is provided thereby reducing the risk of tissue damage. However, practical experience with the catheters have revealed that in particular tissue of a urinary pathway may nevertheless be damaged if the catheter is not carefully inserted or retracted from the pathway.

This problem is addressed by a catheter according to the present invention, wherein the catheter comprises a flexible tube having a distal end region wherein the tube is provided with at least one draining opening, wherein the peripheral edge on the outside of the tube is provided with a curvature for creating a smooth transition between the exterior surface of the tube and the substantially radially oriented cut constituting the

opening side and wherein said curvature is a rounded edge with a curvature radius between 0.2-0.6 mm. By the invention, the opening in the tube is provided with a three-dimensional contour in a curved plane congruent with the curvature of the opening in the cylindrical surface of the tube. Hereby, a smooth catheter is provided where the risk of tissue damage is reduced.

The opening is preferably elongated with a longitudinal length substantially corresponding to the diameter of the tube. The catheter tube may be provided with different diameters so that different sizes of catheters may be provided. The drainage openings in the catheter tube are preferably provided with an angle between the opening side wall and the internal surface of the tube is within the range of 64-90°. This provides the catheter with good drainage properties as well as tissue preserving properties.

The catheter tube is made of a medical grade polymer preferably having a Shore A value in the range of approx. 64 to approx. 100, in particular the polymer may be a thermoplastic material, such as a polyester-type thermoplastic polyurethane (TPU) compound having a Shore A value of approx. 94 ± 3, polyvinylchloride (PVC), preferably having a Shore A hardness ranging from 78 to 85, or polyurethane (PUR). By the invention, it is realised that a variety of materials are suitable for the catheter. For instance, the catheter tube may be of polyvinylchloride (PVC) with a hardness measured in Shore A with a value of 64 to 86, preferably 80 to 85 Shore A.

By the invention, there is also provided a method of making a catheter comprising a polymer tube with openings therein, said method for providing openings in a polymer tube of such catheter comprising the steps of:

providing a tube and punching at least one opening in the tube by advancing a cutting member in a substantially radial direction into the wall of the tube;

manipulating the outer peripheral edge region of the at least one opening by rounding the peripheral edge of the punched opening in the tube by advancing a heated forming member into the opening and thereby providing the edges of the opening with a shape corresponding to the shape of the distal end of the forming member, said forming member having a distal end adapted for engagement a opening of the tube provided adjacent said distal end, wherein said distal end of the forming member is provided with a rounded shoulder transition at the foot of the distal end and

with a protrusion extending from said shoulder transition region, said protrusion having a form fitting the opening in the tube, said rounded shoulder being formed with a contour in a curved plane congruent with the curvature of the opening in the cylindrical surface of the tube.

By finishing the opening in a separate after treatment process, the smooth curvature of the edge of the drainage opening is ensured.

In a preferred embodiment of the method, the loose cut-away material after the punching action is removed from the tube. Hereby, it is ensured that residues from the making of the opening do not drop into the inside of the catheter tube.

According to the invention there is also provided an apparatus for manipulating openings in a polymer tube for manufacturing a catheter, said apparatus comprising a movable frame comprising one or more forming stations, each forming station being adapted for receiving a flexible polymer tube with at least one opening therein through the station and each forming station comprising a forming member, which is mounted in floating arrangement said forming station, said forming member having a distal end adapted for engagement a opening of the tube provided adjacent said distal end, wherein said distal end of the forming member is provided with a rounded shoulder transition at the foot of the distal end and with a protrusion extending from said shoulder transition region, said protrusion having a form fitting the opening in the tube, said rounded shoulder being formed with a three-dimensional contour congruent with the curvature of the opening in the cylindrical surface of the tube, and heating means for said forming member, so that said forming member may be heated to a temperature above the softening point of the polymer of the tube and preferably below the melting point of the polymer material of the tube.

In order to ensure a smooth result of the plastic deformation of the edge region of the opening in the tube, the distal end of the forming member is provided with a rounded shoulder transition at the foot of the distal end and with a protrusion extending from said shoulder transition region, said protrusion having a form fitting the opening in the tube, said rounded shoulder being formed with a three-dimensional contour congruent with the curvature of the opening in the cylindrical surface of the tube.

The rounded shoulder region is provided with a curvature radius between 0.2-0.6 mm and preferably the protrusion is elongated with a longitudinal length substantially corresponding to the axial extension of the opening on the tube.

In the preferred embodiment, the forming member is provided in a forming station which is arranged in a movable frame, and each forming station is adapted for receiving a flexible polymer tube through the station, and whereby the forming member is mounted in floating arrangement a forming station, whereby the forming member is self-aligning when the protrusion is engaging the opening of the tube. This floating arrangement allows for inaccuracies in the positioning of the opening relative to the forming member.

The movable frame preferably comprises an upper section and a lower section where between the at least one forming station is arranged and the upper section is heated to a first temperature, such as 190°-200°C, and the lower section is heated to a second temperature, such as 170°-180°C, which is lower than the first temperature. The holding time of the forming member in contact with the tube is preferably 1 to 5 seconds, more preferably between 1.5 and 2.0 sec. Since there inherently is a heat loss between the movable frame and the shoulder and tip of the forming member, the temperatures applied to the upper and lower sections are somewhat higher than the preferred temperature which is between the softening point of the polymer of the tube and below the melting point of the polymer material of the tube. This ensures that the deformation of the edge does not result in any deterioration of the surface texture and the material of the tube, e.g. burns or uncontrolled deformations. The forming member is made of metal, such as brass or similar heat resistant material that can withstand the applied heat. By the invention it is realised that the temperature may be even above the melting point of the tube material if the holding time is kept very low, such as below 1.5 seconds.

It is realised that the predetermined temperatures and the holding times are selected in accordance with the specific plastic material used for the tube.

In the following the invention is described with reference to some preferred embodiments shown in the accompanying drawings, in which:

Fig. 1 is a side view of a catheter of the kind the present invention concerns;

Fig. 2 is a detailed view of an axial cross-section of the tip of a catheter according to the invention;

Fig. 3 is a detailed view of a radial cross-section of the tip of a catheter according to the invention through the section B-B in fig. 2;

Fig. 4a)-e) are further views of a catheter according to the invention;

Fig. 5 is a perspective view of the catheter of fig. 4;

Fig. 6 is a detailed perspective view of the opening after punching but before the rounding process according to the invention,

Fig. 7 is the same as fig. 6, but after the method of the invention is performed;

Figs. 8-10 are three side views of a forming member in an apparatus for making the catheters according to a preferred embodiment of the invention;

Fig. 11 is a side view of a forming member of a smaller size than the forming member shown in fig. 9;

Fig. 12 is a schematic end view along the catheter tube with two oppositely situated forming members in engagement in the draining openings;

Fig. 13 is a section view along A-A in fig. 12;

Fig. 14 is a schematic side view of the catheter tube with two oppositely situated forming members in engagement in the draining openings;

Fig. 15 is a section view along B-B in fig. 14;

Fig. 16 is a section view along C-C in fig. 14; and

Fig. 17 is a schematic front view of a forming station in a moveable frame in an apparatus according to the invention;

Fig. 18 is a cross-sectional front view of the forming station in fig. 17;

Fig. 19 is a cross-sectional side view of the forming station in fig. 17; and

Fig. 20 is a detailed perspective view of the geometry of the distal end of the forming member and the opening in the tube.

With reference to figures 1 to 5, a catheter according to the invention comprises a flexible tube 1, which is made of a plastic material, preferably polyvinylchloride (PVC) or polyurethane (PUR) and attached to a connector 2. The tube 1 is provided with a number of openings 3 in region of the distal end 4 of the tube 1. This opening 3 serves a drain for collecting fluids outside the tube to flow inside the catheter tube 1 for draining the body space in which the catheter is inserted. The opening 3 has a generally radially oriented side wall 5 (see fig. 3), and which may be provided with an

angular orientation v of between 60-90° relative to the inner surface of the wall of the tube 1 (see fig. 2). The opening 3 may involve a slight indentation 6 into the tube inner space. This indentation 6 may be between 0-0.5 mm. The hole 3 is provided with rounded external edges 7, so that a smooth transition between the opening walls 3 and the surface of the tube 1 is ensured.

The openings 3 are punched in the tube using a punching tool (not shown) or other cutting tool. After the opening 3 is cut in the cutting process, the loose tube wall section is removed leaving an opening in the tube 1 where the opening 3 has a sharp outer edge, as shown in fig. 6. By the finishing process according to the invention, the outer edge is rounded as shown in fig. 5 and fig. 7.

For providing the rounded edge 7 on the opening 3, a moveable frame 20 is used, see figures 17 to 19. The moveable frame includes one or more forming stations, where each forming station is adapted for receiving a flexible polymer tube 1 through the station adjacent a forming member 10. The forming station further includes a holding member 11 to which the forming member 10 is fixed. This member is connected to an upper section 21 of the frame 20 by a spring arrangement 26. The holding member 11 is furthermore pivotably connected to the distal ends of a fork-like member 12, so that the fork-like member 12 and the holding member 11 may pivot relative to each other about an axis A substantially perpendicular to the tube 1 above the tube 1. The fork-like member 12 is at its base pivotably connected to a third member 13, where the two members 12, 13 may pivot about an axis B substantially parallel to the tube 1 below the tube 1. This third member 13 is then pivotably connected to a lower member 14 allowing these members 13, 14 to pivot about an axis C substantially perpendicular to the tube 1. This lower member 14 is preferably vertically slidably secured to a lower section 22 of the frame via a spring 25. When the frame 20 is moved relative to the tube 1, the forming member 10 is moved in engagement with the opening 3 in the tube 1. By the pivoting arrangements, the forming member 10 is floatingly arranged in the frame whereby the forming member 10 may be self-centering in the opening 3.

With reference to the figures 8-10 and 11, the forming member 10 has a distal end 33 adapted for engagement the opening 3 of the tube 1 provided adjacent the distal end 33. The distal end 33 of the forming member 10 is provided with a rounded shoulder transition 32 at the foot of the distal end 33 and with a protrusion 31 extending from the

shoulder transition region 32. The protrusion 31 has a form fitting the opening 3 in the tube 1. The rounded shoulder 32 is formed with a three-dimensional contour congruent with the curvature of the opening 3 in the cylindrical surface of the tube 1. It is important to realise that the edge 7 of the opening on the tube 1 extend in a curved plane, i.e. the edge 7 has a three-dimensional extension. As shown in figs. 9 and 11, the forming member 10 may be provided with different distal ends in order to adapt a forming member to a specific tube and opening size.

By applying heat to the frame and thereby to the members in the forming station, which are all made of a thermally conductive material, preferably steel or similar metal, the forming member 10, which is made of brass or the like, is heated to a temperature above the softening point of the polymer of the tube and preferably below the melting point of the polymer material of the tube. A first heat source 23 is applying heat to the upper section 21 of the frame 20 and a second heat source 24 is applying heat to the lower section 22 of the frame 20. The first temperature may preferably be between 180-200 °C ± 10 °C and the second temperature may be between 170-190 °C ± 10 °C. The diameter of the tube may be between 2.0 - 6.0 mm and the temperature applied is preferably in the lower range of the temperature range if the diameter is small. The temperature ranges as well as the holding times may vary depending on the type of material and the thickness of the tube wall as well as the diameter of the tube.

When heat is applied to the forming station and thereby to the forming member 10 the forming member 10 is advanced into engagement with the opening 3 in the tube 1 for a predetermined period of time, preferably between 1.5-2.0 seconds. The temperatures applied and the times of engagement, i.e. the holding time, are selected in accordance with the tube material and the tube dimensions. The temperature may be even above the melting point of the tube material if the holding time is kept very low. Hereby, the edge 7 is rounded in a plastic deformation process as the heated forming member 10 is moved into engagement in the opening 3. The protrusion 31 fits into the opening 3 and as the protrusion aligns in the opening 3, the rounded transition 32 thereby advances correctly towards the edge region and thereby creates the desired rounding of the edge 7. The floating arrangement described earlier facilitates the alignment of the forming member 10 in the opening.

As shown in figures 12 to 16, two openings in a catheter made can be processed simultaneously by having two movable frames (not shown) adjacent each other so that a first forming member 10' is advanced into contact with an opening from a first side of the tube and a second forming member 10'' is advanced into contact from a side opposite the first side.

The form of the edge 7 of the opening 3 in the tube 1 is determined by the geometry of the distal end of the forming member 10, in particular the shoulder transition 32 but also the protrusion 31. The resulting tube opening 3 may be provided with an inclined side surface 5 with an angle *v* between 60°-90° in the axial direction between the opening side and the inner surface of the tube 1, see fig. 2. As shown in fig. 3, the side walls 5 of the opening 3 may have a radial direction in the cross-sectional direction. Moreover, a slight inwardly extending indentation 6 having a radial extension between 0-0.48 mm is also provided in the tube.

Examples

For different diameter sizes, tests have been made for finding a suitable relationship between temperature, holding time and pressure of the forming member 10. In practise, the pressure may be predetermined as the insertion depth of the distal end of the forming member 10 and may be controlled in relation to the predetermined measurements and tolerances. By testing, the chosen combinations of temperature and time listed in table 1 below are found stabile for manufacturing and optimal with respect to minimizing the process time.

The parameters for the tests were:

- The tube material was ESTANE 58212 TPU which is a thermoplastic polyurethane compound with a glass transition temperature of -25°C, an extrusion temperature of 200-210°C and an injection moulding temperature of 195-205°C.
- The shape and the temperature of the distal end of the forming member.
- The time the forming member is making contact with the tube.

- The insertion depth of the distal end of the forming member in the tube, referred to as pressure).

Table 1:

ESTANE® 58212 TPU		
Diameter size	**Temp.**	**Time**
CH08	170 °C	1.5 s
CH10	180 °C	1.7 s
CH12	180 °C	1.7 s
CH14	180 °C	1.7 s
CH16	180 °C	1.7 s
CH18	180 °C	2.0 s

Compared to the parameters in table 1, by lower temperatures or shorter time or lower pressure (i.e. shorter insert distance) it was found that the rounding was not complete and/or the deformation was not permanent.

Compared to the parameters in table 1, by larger temperatures, the material became too liquidized and melted and by longer time or larger pressure resulted in elevated edges in the transition between the tube and the forming member 10.

In relation to the geometric shape of the distal end of the forming member 10 it was found of imperative importance that the rounding of the edge is a stamp of the forming member by a certain deformation of the tube. Accordingly, the shape of the distal end of the forming member is of most importance for obtaining a satisfactory rounding of the edge of the catheter opening 3. By matching the three-dimensional contour of the edge on the tube when shaping the distal end of the forming member, i.e. with the same dimensions, rounding and sizes, a satisfactory result was considered achieved. Moreover, by forming the distal end of the forming member with appropriate angles and transitions it was found further ensured that no “sharp” edges would occur on the tube.

As indicated in fig. 20, the contour of the shoulder transition portion 32 of the distal end 33 of the forming member 10 are shaped with two end sections 34 with a “straight” section 35 therebetween. The corresponding edge contours are marked on the tube

opening 3 by 34' and 35', respectively. Whereas the straight section 35 is substantially in the same plane, due to the cylindrical shape of the tube and the central straight shape of the opening when viewed from the Y-axis, the ends 34, 34' are curved out of this plane because of the rounded, semi-circular end portions of the opening again when viewed from the Y-axis. This three-dimensional shape of the distal end of the forming member 10 is found particularly advantageous in order to achieve an opening 3 with an entirely and truly smooth contour.

This geometry ensures that an unacceptable deformation on the inside of the tube is prevented.

The resulting rounded edge along the opening in the catheter tube is in an X-Y and/or Y-Z plane. When viewing the catheter in the Z-direction, such as shown in fig. 2, figs. 4c and 4e, it becomes apparent that the contour of the edge of the opening 3 is curved in an X-Y plane perpendicular to the rounded edge plane at any given place on along the opening. This curvature of the side contour of the opening is due to the cylindrical form of the tube. This in turn means that when the opening is cut the central section, i.e. the straight section 35' in fig. 20, becomes lower that the outer contour of the tube view viewed from the side, e.g. as schematically shown in figs. 4a, 4c and 4e. The end sections of the opening, i.e. the extremes in the X direction of the opening, curve outwards towards the straight outer contour of the tube itself. By the invention it is realised that it is important to acknowledge and pay attention to this geometric shape when forming the rounded edges on the opening in order to avoid sharp edges and to ensure a truly smooth transition between the outer surface of the cylindrical tube and the inner side wall 5 of the opening 3.

Above, the invention and the different aspects thereof are described with reference to some preferred embodiment. However, by the invention it is realised that other variations and equivalent solutions may be provided without departing from the scope of the invention as defined in the accompanying claims, such as other suitable materials and other process parameters, such as temperature and time, may be chosen in order to achieve a satisfactory result when using tubes in a predetermined material.

The catheter according to the invention may be a urinary catheter, a tracheostomy catheter or any other type of catheters for insertion into a body cavity for draining fluids.

Claims

1. A catheter for medical purposes, such as for insertion into a body opening for draining fluids, wherein the catheter comprises a flexible tube having a distal end region wherein the tube is provided with at least one draining opening, characterised in that the peripheral edge on the outside of the tube is provided with a curvature for creating a smooth transition between the exterior surface of the tube and the substantially radially oriented cut constituting the opening side and wherein said curvature is a rounded edge with a curvature radius between 0.2-0.6 mm, and said rounded edge is formed in a curved plane following the curvature of the opening in the cylindrical surface of the tube.

2. A catheter according to claim 1, wherein the opening is elongated with a longitudinal length substantially corresponding to the diameter of the tube.

3. A catheter according to claim 1 or 2, wherein the tube is made of a medical grade polymer having a Shore A value in the range of approx. 64 to approx. 100.

4. A catheter according to claim 3, wherein the polymer is a thermoplastic material, preferably a medical grade material, such as a polyester-type thermoplastic polyurethane (TPU) compound, polyvinylchloride (PVC), preferably having a Shore A hardness ranging from 64 to 85, or polyurethane (PUR).

5. A catheter according to any of the preceding claims, wherein the angle between the opening side and the internal surface of the tube is within the range of 64-90°.

6. A method of making a catheter comprising a polymer tube with openings therein, said method for providing openings in a polymer tube of such catheter comprising the steps of:

providing a tube and punching at least one opening in the tube by advancing a cutting member in a substantially radial direction into the wall of the tube;

manipulating the outer peripheral edge region of the at least one opening by rounding the peripheral edge of the punched opening in the tube by

advancing a heated forming member a predetermined distance into the opening and thereby providing the edges of the opening with a shape corresponding to the shape of the distal end of the forming member, said forming member having a distal end adapted for engagement a opening of the tube provided adjacent said distal end, wherein said distal end of the forming member is provided with a rounded shoulder transition at the foot of the distal end and with a protrusion extending from said shoulder transition region, said protrusion having a form fitting the opening in the tube, said rounded shoulder being formed with a contour in a curved plane congruent with the curvature of the opening in the cylindrical surface of the tube, and

holding said heated forming member in said advanced position for a predetermined holding time before retracting the forming member.

7. A method according to claim 6, whereby loose cut-away material is removed after the punching action.

8. A method according to claim 6 or 7, whereby the forming member is provided in a forming station which is arranged in a movable frame, and each forming station is adapted for receiving a flexible polymer tube through the station, and whereby the forming member is mounted in floating arrangement a forming station, whereby the forming member is self-aligning when the protrusion is engaging the opening of the tube.

9. A method according to any of claims 6 to 8, whereby the movable frame comprises an upper section and a lower section where between the forming station is arranged and the upper section is heated to a first temperature, such as 190-200 °C, and the lower section is heated to a second temperature, such as 170-180 °C, which is lower than the first temperature, and whereby the predetermined holding time is preferably 1 to 5 seconds, more preferably 1.5 to 2 seconds.

10. A method according to any of claims 6 to 9, whereby the distal end of the forming member is provided with a rounded shoulder transition with a curvature radius between 0.2-0.6 mm at the foot of the distal end and with a protrusion extending form said shoulder transition region which is inserted into the opening of the tube, and whereby the protrusion is provided with a form fitting the opening in the tube, so that the

rounded shoulder is formed with a three-dimensional contour congruent with the curvature of the opening in the cylindrical surface of the tube.

11. A method according to any of claims 6 to 10, whereby the tube is made of a medical grade polymer having a Shore A value in the range of approx. 64 to approx. 100, and whereby the forming member is heated to a temperature above the softening point of the polymer of the tube and below the melting point of said polymer.

12. An apparatus for manipulating openings in a polymer tube for manufacturing a catheter, said apparatus comprising a movable frame comprising one or more forming stations, each forming station being adapted for receiving a flexible polymer tube with at least one opening therein through the station and each forming station comprising:

a forming member, which is mounted in floating arrangement said forming station,

said forming member having a distal end adapted for engagement a opening of the tube provided adjacent said distal end, wherein said distal end of the forming member is provided with a rounded shoulder transition at the foot of the distal end and with a protrusion extending from said shoulder transition region, said protrusion having a form fitting the opening in the tube, said rounded shoulder being formed with a three-dimensional contour congruent with the curvature of the opening in the cylindrical surface of the tube, and

heating means for said forming member, so that said forming member may be heated to a temperature above the softening point of the polymer of the tube and preferably below the melting point of the polymer material of the tube.

13. An apparatus according to claim 12, wherein the forming member is self-aligning when the protrusion is engaging the opening of the tube.

14. An apparatus according to claim 12 or 13, wherein the movable frame comprises an upper section and a lower section where between the at least one forming station is arranged.

15. An apparatus according to any of claims 12 to 14, wherein the forming member is made of metal, such as brass.

16. An apparatus according to any of claims 12 to 15, wherein the movable frame comprises an upper section and a lower section where between the forming station is arranged and the upper section is heated to a first temperature, such as 190-200°C, and the lower section is heated to a second temperature, such as 170-180°C, which is lower than the first temperature, and whereby the predetermined holding time is preferably 1 to 5 seconds, more preferably 1.5 to 2 seconds.

17. An apparatus according to any of claims 12 to 16, wherein the rounded shoulder region is provided with a curvature radius between 0.2-0.6 mm.

18. An apparatus according to any of claims 12 to 16, wherein the protrusion is elongated with a longitudinal length substantially corresponding to the axial extension of the opening on the tube.

19. An apparatus according to any of claims 12 to 18, wherein the tube is made of a medical grade polymer, such as a thermoplastic material, such as a polyester-type thermoplastic polyurethane (TPU) compound having a Shore A value in the range of 80 to 100, preferably approx. 94 ± 3, polyvinylchloride (PVC), preferably having a Shore A hardness ranging from 64 to 85, or polyurethane (PUR).

20. Use of an apparatus according to any of claims 12 to 19 for the performance of a method according to any of claims 6 to 11 for the manufacture of a catheter according to any of claims 1 to 5.

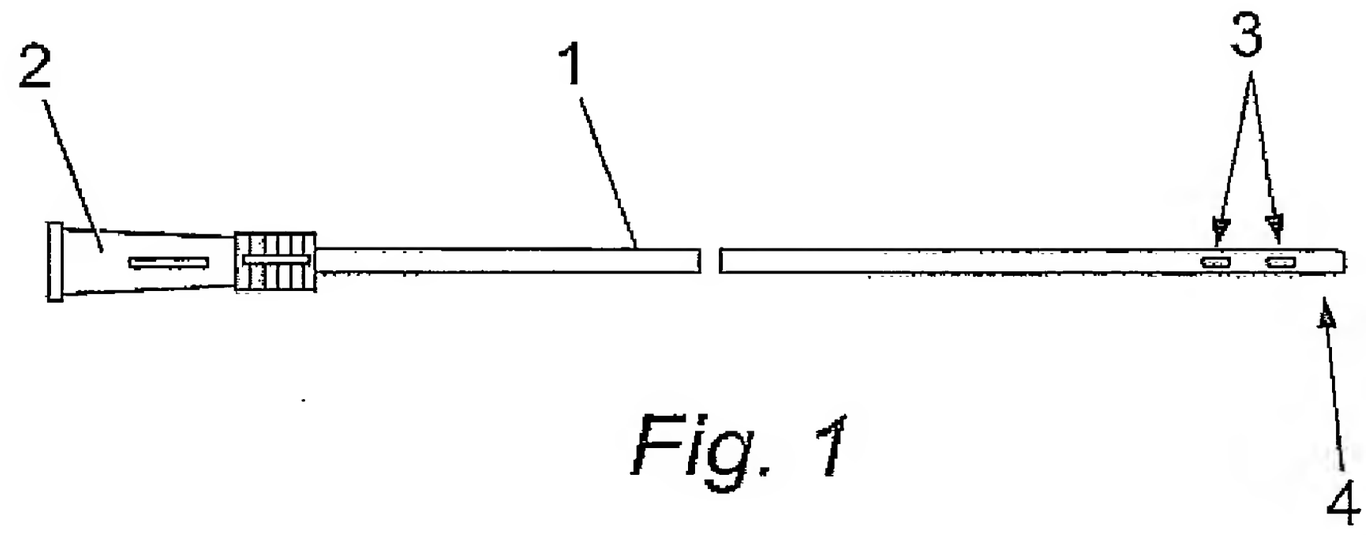


Fig. 1

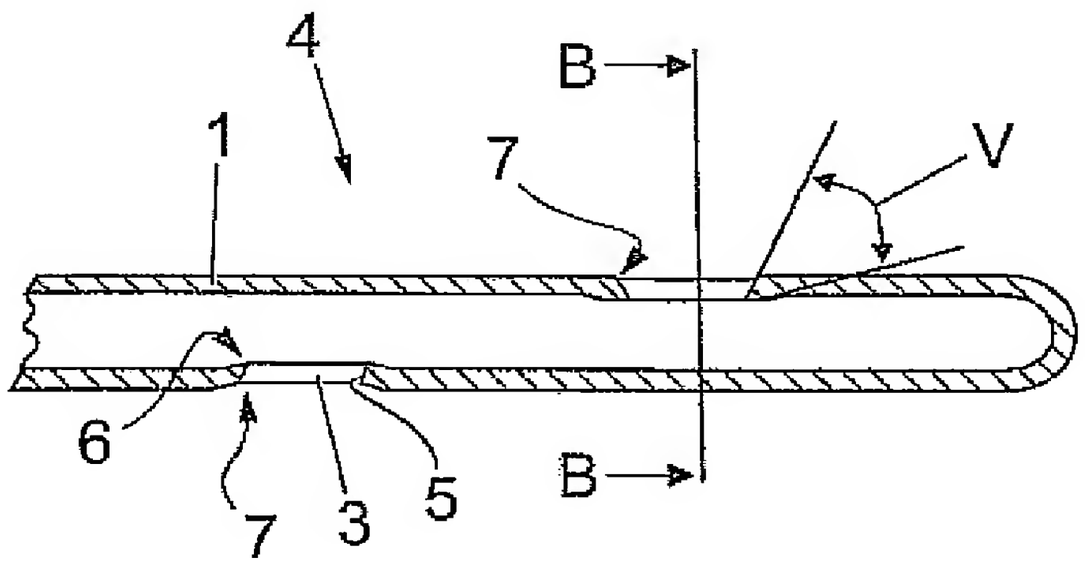


Fig. 2

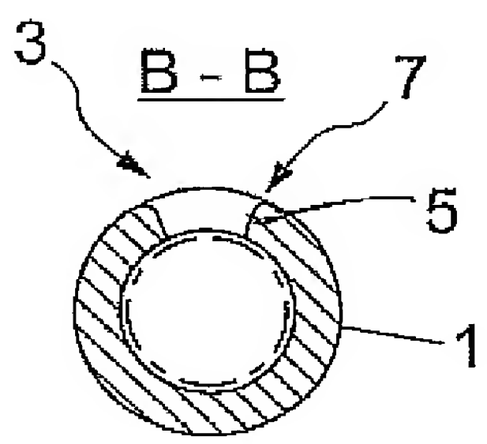


Fig. 3

Fig. 4a

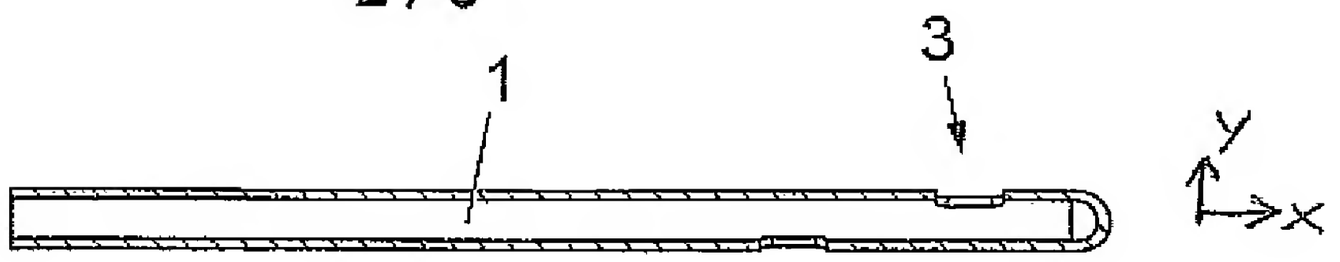


Fig. 4b

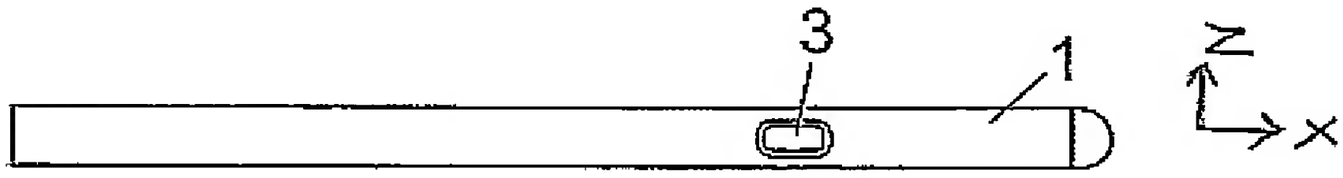


Fig. 4c

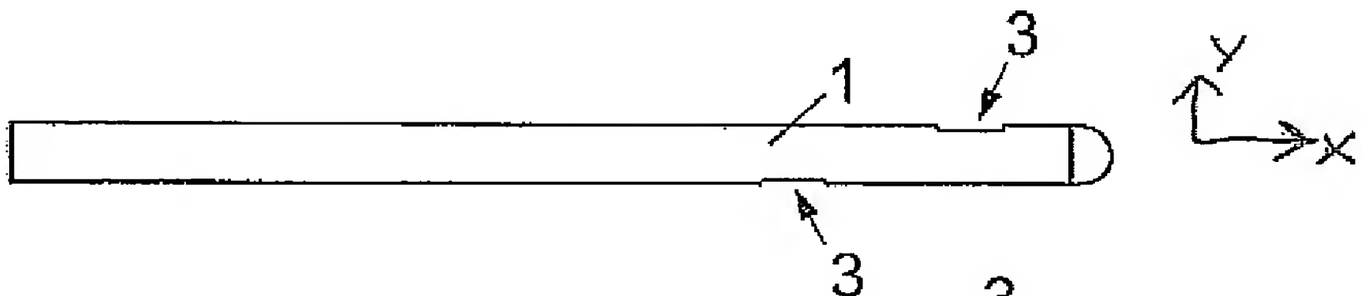


Fig. 4d

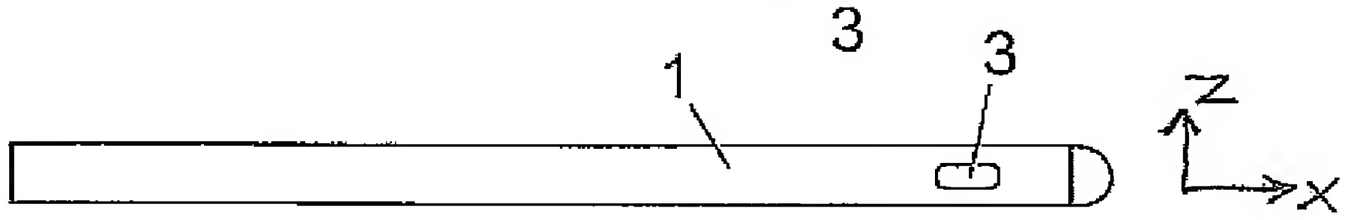


Fig. 4e

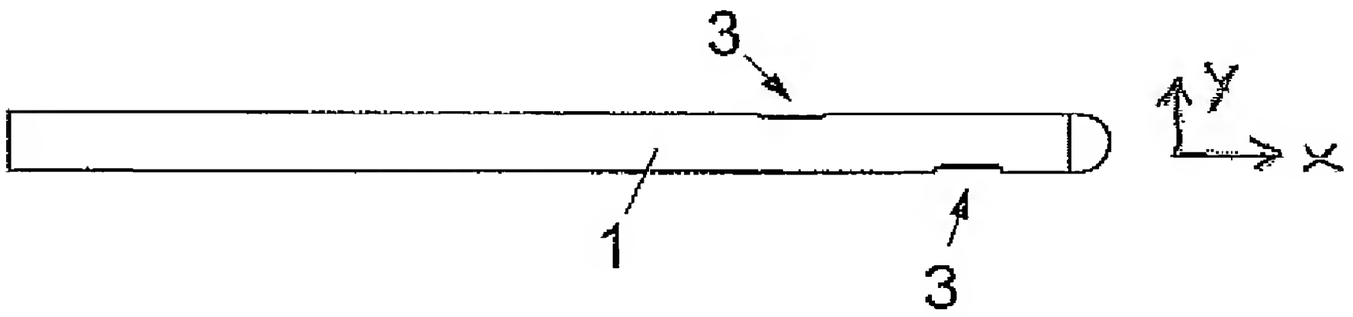
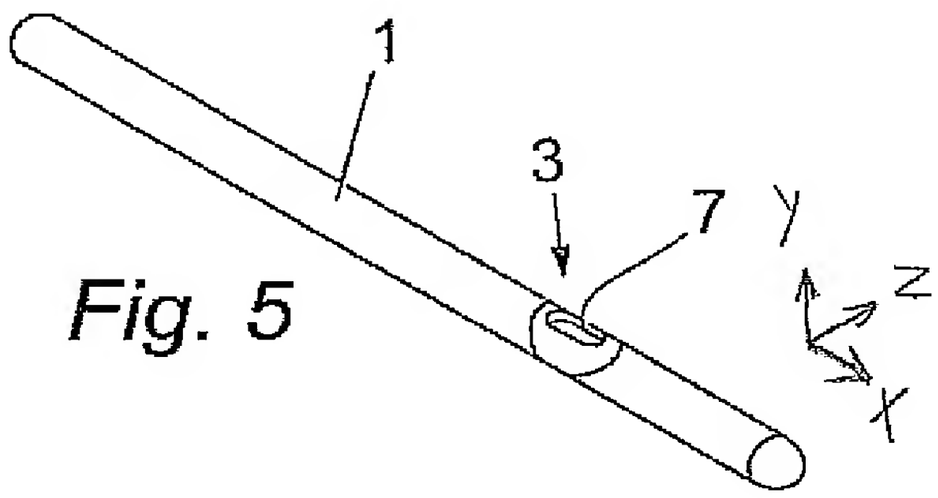


Fig. 5



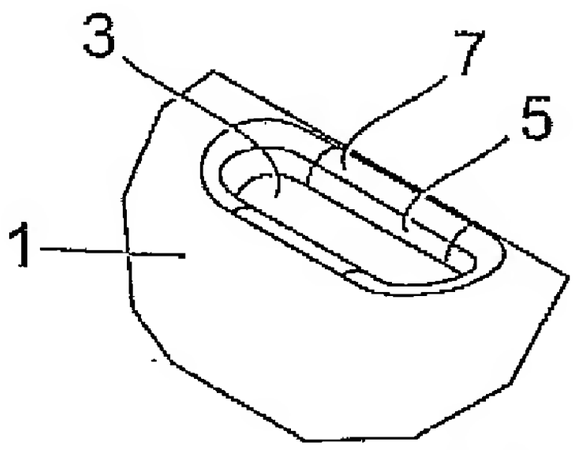


Fig. 7

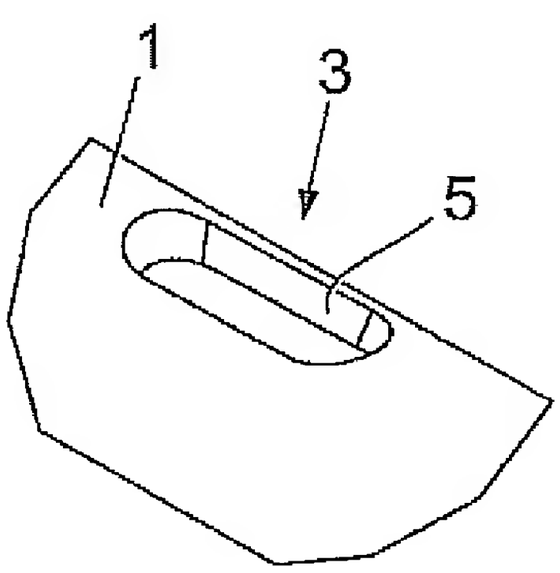


Fig. 6

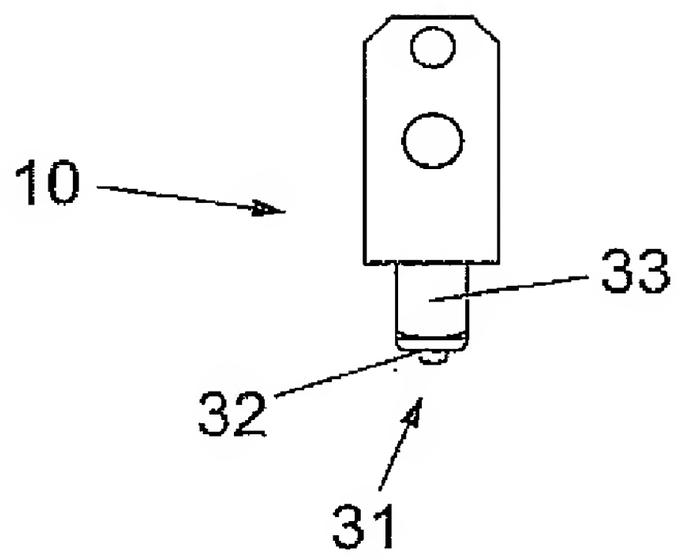


Fig. 8

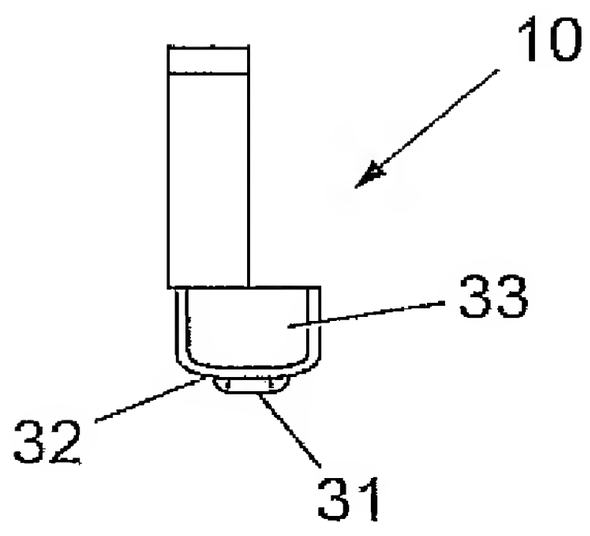


Fig. 9

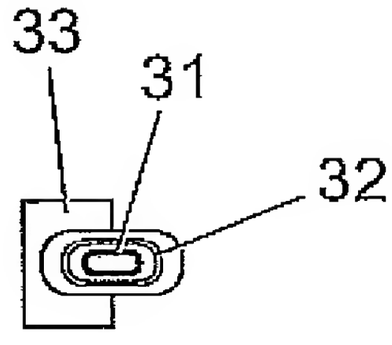


Fig. 10

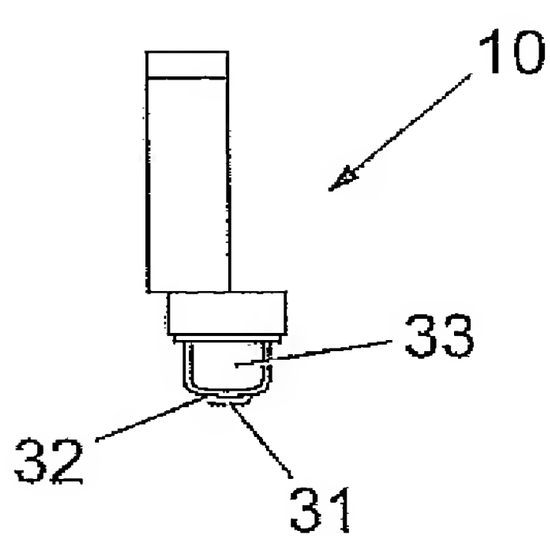


Fig. 11

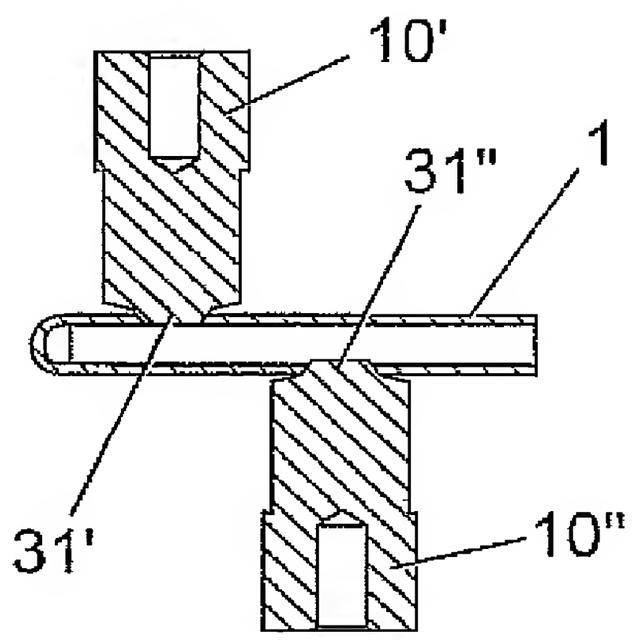


Fig. 13

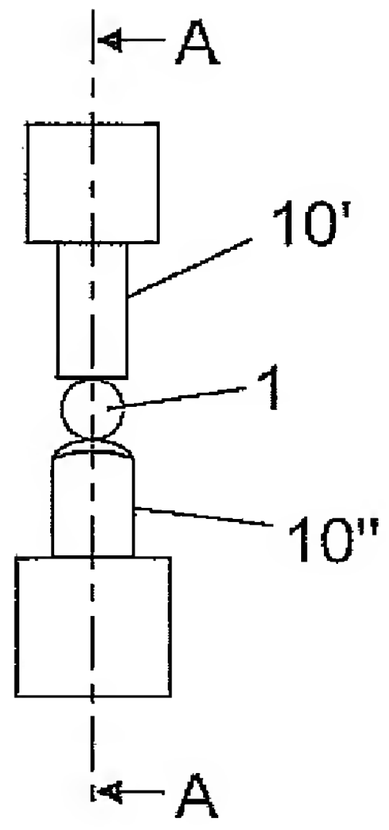
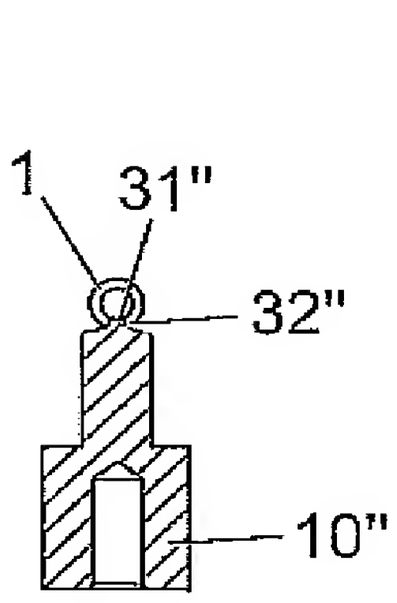


Fig. 12



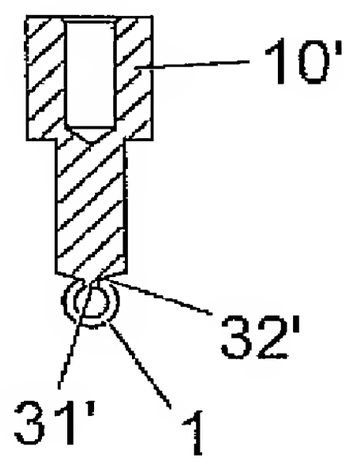


Fig. 16

Fig. 15

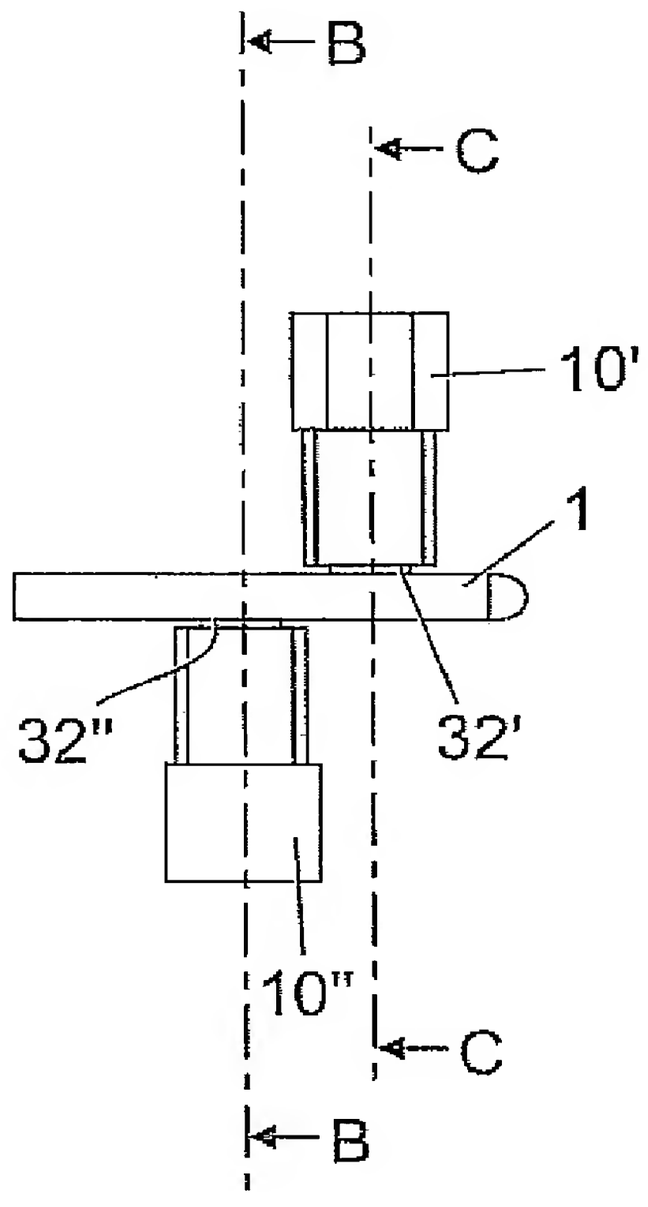


Fig. 14

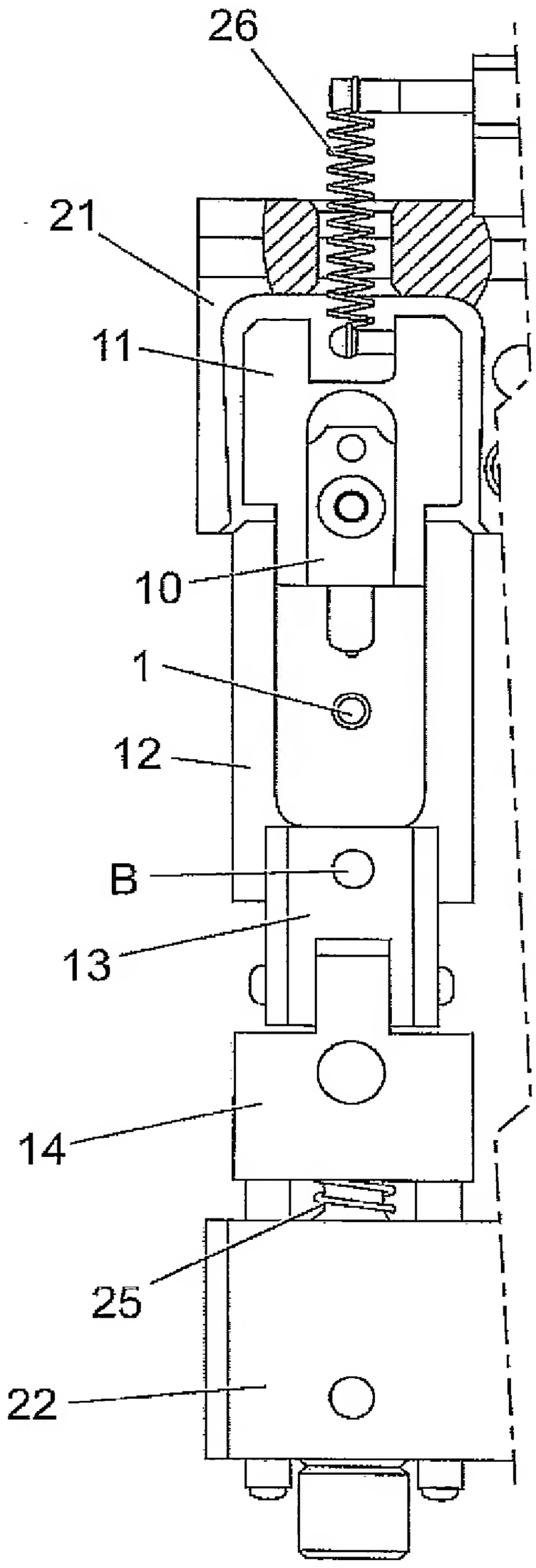


Fig. 17

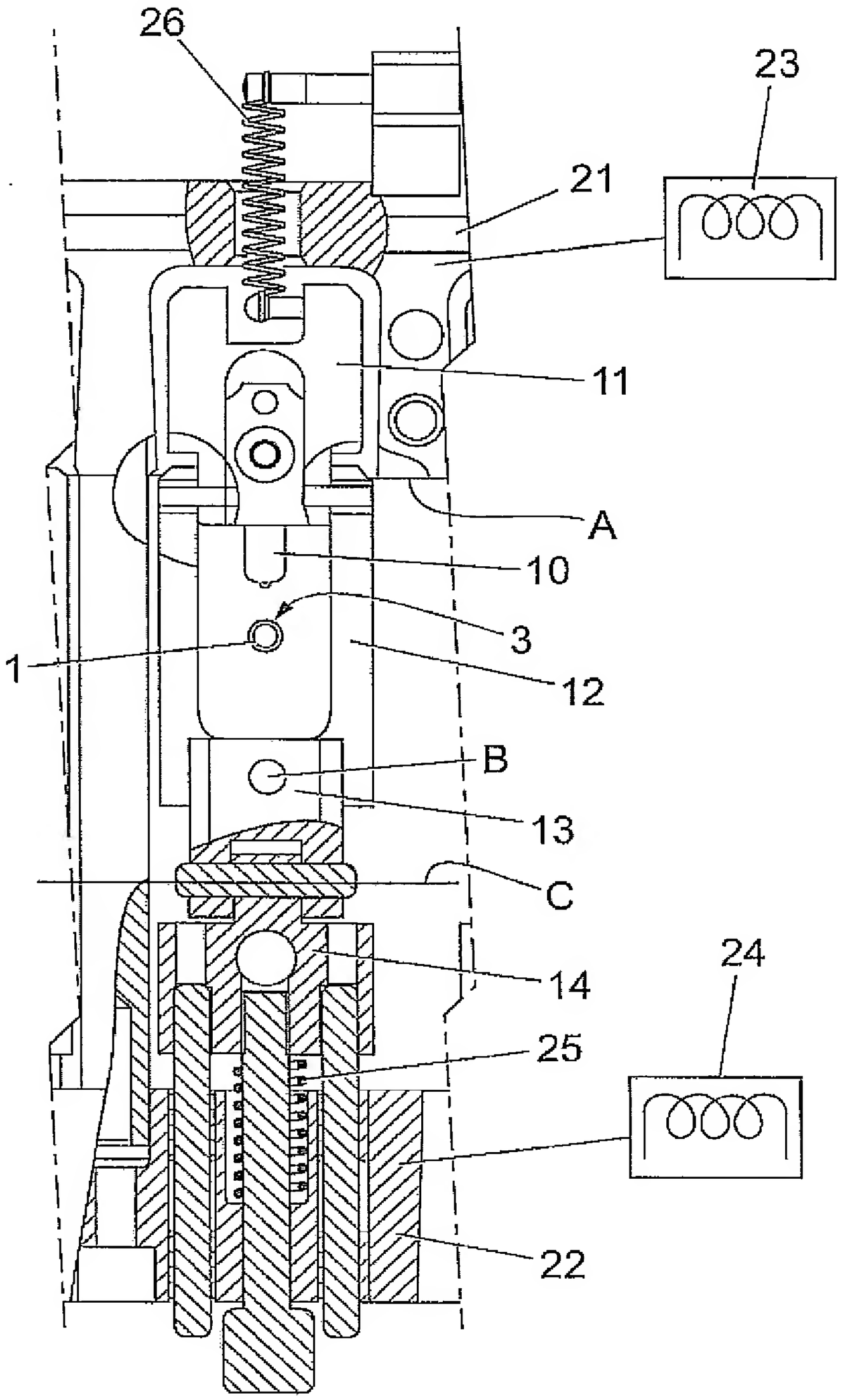


Fig. 18

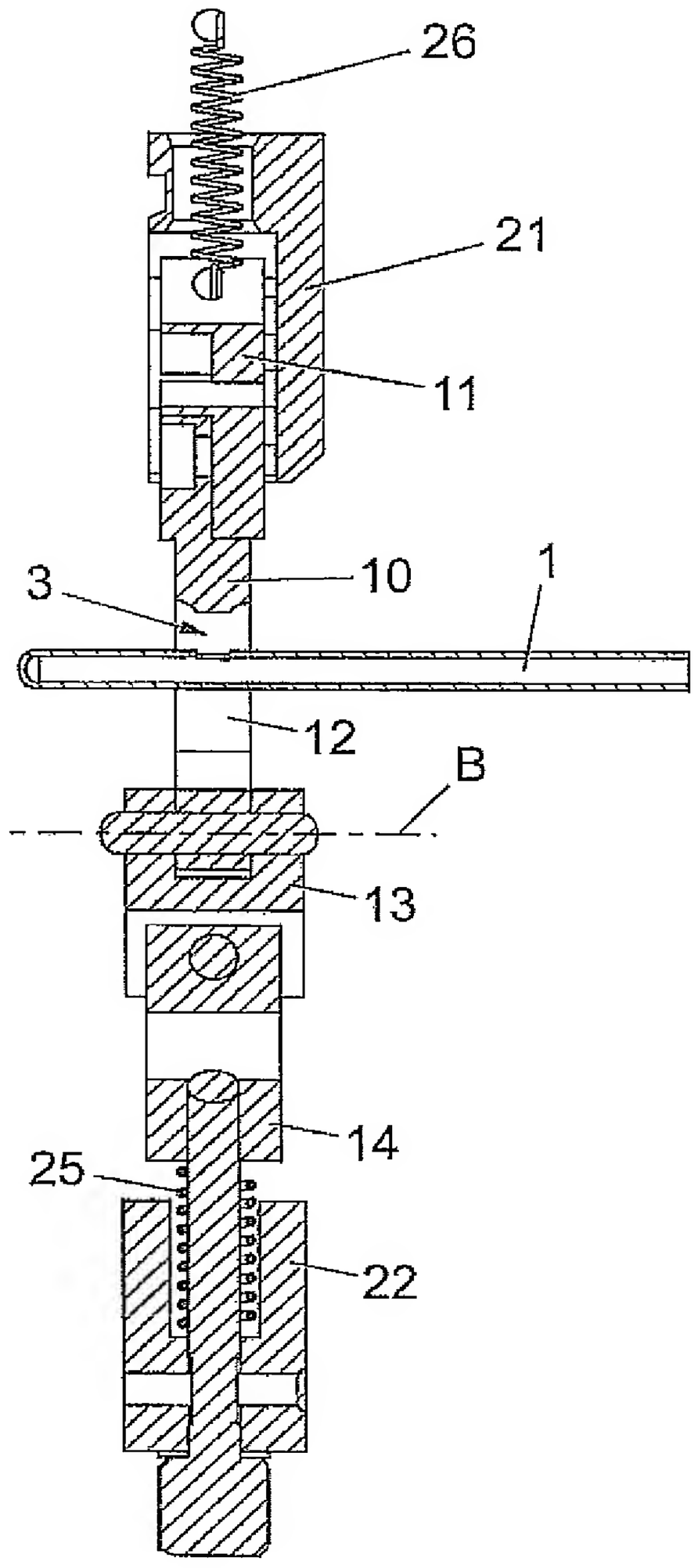


Fig. 19

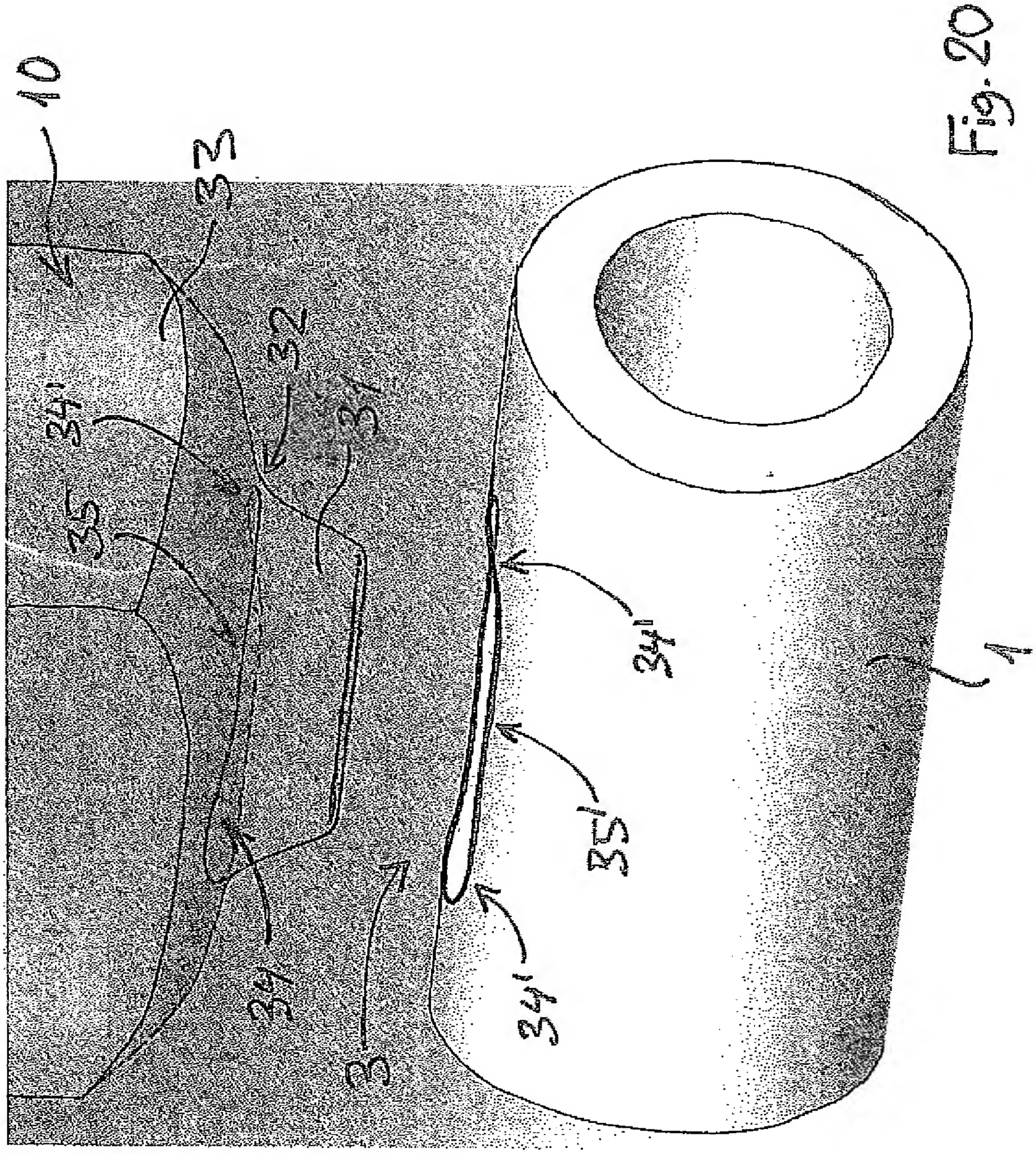


Fig. 20

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/054549

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00 B26F1/00 B26F1/02 A61M27/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M B26F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2 972 779 A (COWLEY CALVIN C) 28 February 1961 (1961-02-28) column 1, line 15 - column 1, line 18 column 2, line 1 - column 4, line 50; figures 1-14	1-8,10, 12-15, 17-20
X	US 2005/192560 A1 (WALLS JAMES A [US] ET AL) 1 September 2005 (2005-09-01)	1-5
A	page 1, paragraph 3 page 1, paragraph 13 - page 2, paragraph 14 page 3, paragraph 39 - page 5, paragraph 57; claim 1; figures 1-13	6,12

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2008	05/06/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rolland, Philippe

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/054549

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/193143 A1 (SAUER MANFRED [DE]) 30 September 2004 (2004-09-30) page 1, paragraph 2 page 1, paragraph 8 page 1, paragraph 12 - page 1, paragraph 13 page 2, paragraph 25 page 3, paragraph 33 - page 3, paragraph 37; figures 1-3	1-8, 11-15, 17-20
X	US 4 259 276 A (RAWLINGS DEREK S) 31 March 1981 (1981-03-31) column 1, line 5 - column 1, line 30 column 1, line 58 - column 2, line 11 column 2, line 22 - column 3, line 27; figures 1-3	1,3-8, 12-15, 19,20
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A	US 4 617 019 A (FECHT DAVID C [US] ET AL) 14 October 1986 (1986-10-14) column 1, line 6 - column 1, line 7 column 2, line 3 - column 2, line 7 column 2, line 67 - column 4, line 1; figures 1,10 column 5, line 42 - column 5, line 62; figure 9 claims 1-11	1,6,12
A	US 2005/165382 A1 (FULFORD ANTHONY [GB]) 28 July 2005 (2005-07-28) page 1, paragraph 14	3

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Information on patent family members

International application No
PCT/EP2008/054549

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